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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,199	09/24/2001	Mitsuaki Yamamoto	213966US0PCT	6427

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	**PAPER NUMBER**
1641	

NOTIFICATION DATE	DELIVERY MODE
10/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/926,199	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-71,73-84 and 86-88* is/are pending in the application.

4a) Of the above claim(s) *64-70,73-84 and 86-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-63 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment, filed 10/5/2009, is acknowledged and has been entered. Claims 62-63 and 71 were amended. Claims 62-71, 73-84, and 86-88 are pending in the application, with claims 64-70, 73-84, and 86-88 currently withdrawn. Claims 62-63 and 71 are subject to examination below in light of the elected species of **digitonin.**

Priority

2. The present application was filed as a National Stage (371) entry of PCT Application No. PCT/JP00/01663, filed 3/17/2000. Acknowledgment is also made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Application No. 1180503, filed on 3/24/1999 in Japan.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 62-63 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerscher et al. (U.S. 4,851,335) in view of Hino et al. (U.S. 5,773,304) and Kishi et al. (JP 9-313178; see also the attached machine translation obtained retrieved on 4/12/09 from http://www4.ipdl.inpit.go.jp and the attached partial translation from the JPO as retrieved via the EAST database on 4/12/09) and in light of the evidence of Hirai et al. (U.S. 4,940,660, of record).

Kerscher et al. which teaches a reagent for the specific determination of cholesterol of the HDL fraction which comprises cholesterol oxidase and cholesterol esterase, a non-ionic detergent, and optionally also polyethylene glycol (see especially at column 3, line 53 to column 4, line 52; and claims 1 and 10 in particular). The non-ionic detergent may be Triton X-100 (column 10, lines 59-60).

Hirai et al. provides evidence that Triton X-100 is the trade name for the detergent polyoxyethylene (10) octylphenyl ether as recited instantly (see column 6, lines 55-57). Therefore, in light of the evidence of Hirai et al., the detergent taught by Kerscher et al. reads on the claimed detergent.

The teachings of Kerscher et al. differ from the claimed invention in that the reference fails to specifically teach that the reagent also includes the elected species of **digitonin**.

Hino et al. teach that when measuring cholesterol, the enzymes cholesterol esterase and cholesterol oxidase may be combined and used as enzyme reagents. Alternatively, cholesterol esterase and cholesterol dehydrogenase may be combined (column 3, lines 33-39).

Kishi et al. teach that although methods of using cholesterol dehydrogenase for the purpose of measuring cholesterol were known, this enzyme is unstable (see especially the attached machine translation at [0003]). To solve this problem, Kishi et al. teach stabilized compositions that include a glycoside such as digitonin in addition to cholesterol dehydrogenase, in order to improve the stability and activity of the enzyme. See the machine translation at [0001]-[0003], [0008]-[0012] and also the attached JPO translation at pages 1-2, "Solution". Such stabilized enzyme compositions can be used for determining cholesterol in blood [ibid].

The Courts have ruled that art-recognized equivalence between embodiments provides a strong case of obviousness in substituting one material for another. See MPEP 2144.06:

In the instant case, the teachings of Hino et al. indicate that cholesterol esterase can be combined with either cholesterol oxidase or alternatively with cholesterol dehydrogenase in order to form an enzyme reagent capable of being used in cholesterol determination.

Because cholesterol oxidase and cholesterol dehydrogenase were therefore recognized in the prior art to be functional equivalents for the purpose of cholesterol determination, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute cholesterol dehydrogenase for cholesterol dehydrogenase in the reagent composition for determination of cholesterol determination of Kersher et al.

In addition, when employing cholesterol dehydrogenase in place of cholesterol oxidase, it would have been further obvious to include a glycoside such as digitonin (as taught by Kishi et al.) because Kishi et al. taught that such an additive stabilizes cholesterol dehydrogenase. Therefore, one would be motivated to include digitonin as a known additive to cholesterol

dehydrogenase-containing compositions so as to obviate known stability issues associated with this enzyme and to improve the activity of this enzyme in the composition.

Response to Arguments

6. Applicant's arguments filed 10/5/2009 have been fully considered but they are not persuasive.

7. Applicant argues that there is no suggestion in Kishi et al. that the addition of digitonin would allow for HDL cholesterol to selectively react with enzyme (Reply, pages 8-9).

This is not found persuasive because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In particular, although Kishi et al. does not specifically mention using digitonin for the purpose of allowing selective reactivity with HDL cholesterol, it is maintained that it would nonetheless have been obvious to include digitonin in the reagent of Kerscher al. and Hino et al. for the reasons taught by Kishi et al.--namely, to improve enzyme stability and activity when determining cholesterol, which is the purpose of the reagent of Kerscher et al. and Hino et al.

Applicant further argues that the cited references fail to suggest the selective quantitative determination of HDL cholesterol from blood serum with digitonin (Reply, page 9).

This is not found persuasive for reasons of record. In particular, Kerscher et al. teaches a reagent for determining the concentration of the cholesterol of the HDL fraction in particular (see especially column 3, line 53). Although Kerscher et al. does not specifically teach inclusion of

digitonin, when taken together with the teachings of Kishi et al. (which teaches inclusion of digitonin as discussed above) and Hino et al., the references when taken as a whole do therefore teach a digitonin-containing reagent for determining the concentration of the cholesterol of the HDL fraction.

Furthermore, Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In the instant case, the recitation in the preamble of a reagent "for selective quantitative determination of HDL cholesterol" is directed to the intended use of the claimed reagent. As such, the prior art need not teach the actual use of the reagent "for selective quantitative determination of HDL cholesterol". Rather, if the reagent suggested by the prior art is merely capable of performing this intended use, as determination of obviousness would be warranted even if the prior art were completely silent in regards to HDL determination (which is not the case here).

Notwithstanding the above, therefore, the reagent suggested by the teachings of Kerscher et al., Kishi et al., and Hino et al. meets the claim simply in teaching a reagent composition having all necessary ingredients, as such a composition would be capable of being used for the intended purpose recited in the preamble.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached at (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641

/Christopher L. Chin/
Primary Examiner, Art Unit 1641